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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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10/555,289

07/03/2006

Jean-Luc Georges Battini

0508-1149

9338

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7590

11/06/2008

YOUNG & THOMPSON

209 Madison Street

Suite 500

ALEXANDRIA, VA 22314

EXAMINER

MOSHER, MARY

ART UNIT

PAPER NUMBER

1648

MAIL DATE

DELIVERY MODE

11/06/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--|---------------------------------------|--|
| Office Action Summary | Application No. 10/555,289 | Applicant(s) BATTINI ET AL. | |
| | Examiner Mary E. Mosher, Ph.D. | Art Unit 1648 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>12/22/05, 11/02/05</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Rejections - 35 USC § 112

Claims 16-20, 22-24 provide for the use of various peptides and nucleic acids, but, since the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections - 35 USC § 101

Claims 16-20, 22-24 are is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112

Claims 16-29 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for in vitro diagnosis of cells overexpressing GLUT1 on cell surfaces and diagnosing tumors, does not reasonably provide enablement for preventing or treating pathologies, targeting drug vectors, or diagnosing inflammatory conditions, immune or autoimmune disorders, or central nervous system disorders. The specification does not enable any person skilled in the

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art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

There are several aspects to this rejection.

Applicant has shown, with working examples, that the receptor-binding domain of HTLV envelope protein binds GLUT1. Therefore, no undue experimentation would be involved in a method which uses binding of the protein (or a suitable fragment of it) to detect GLUT1 on cell surfaces and to quantitate the amount of GLUT1 on cell surfaces. However, considerably more effort would be involved in establishing that the amount of GLUT1 on cell surfaces is sufficient to diagnose the broad range of pathologies recited in the claims. The prior art contains considerable recognition of elevated GLUT1 expression in a variety of neoplasms, and a considerable knowledge of appropriate biopsy techniques. The state of the art is not nearly as developed for the remaining conditions recited in the claims. The specification does not teach where to obtain appropriate cell samples for diagnosing inflammatory or immune pathologies, or teach the levels which distinguish between normal and pathological cells. The specification also fails to teach how to diagnose a GLUT1 deficiency syndrome by detecting an overexpression of GLUT1. Therefore, considering the quantity of experimentation required, the state of the art, the limited teachings in the specification, and the absence of working examples, it is concluded that undue experimentation would be required to practice the full scope of diagnostic methods, as claimed.

In regard to preventing or treating pathologies, the state of the art is even less advanced than the diagnostic art. Although the art recognizes that aberrations in GLUT1

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activity occur in a number of circumstances, the prior art does not teach that GLUT1 activity is the causative agent for the pathologies listed in the claims. Therefore, the efficacy of inhibiting GLUT1 activity is unpredictable in regard to any prophylactic or therapeutic benefit. Furthermore, GLUT1 is active in many tissues, and one skilled in the art would expect side effects from systemic inhibition, without being able to predict what the side effects might be. The practitioner in the medical arts would require extensive guidance for each disease in how much binding peptide to use, how to administer it in order to achieve an effective treatment, and how to deal with side effects. The same logic applies to the use of drugs targeted by a GLUT1 binding peptide. Therefore, considering the state of the art, the unpredictability of the medical art, the limited teachings in the specification, and the absence of working examples, it is concluded that undue experimentation would be required to practice any of the preventive or therapeutic methods claimed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 30 is rejected under 35 U.S.C. 102(b) as being anticipated by Palker et al (Journal of Virological Methods 18:243-255, 1987). Claim 30 is drawn to a kit but requires only a single component, GLUT1 binding polypeptide from the envelope protein of a primate T cell leukemia virus. Palker teaches the component, in teaching purified

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gp46 of HTLV-1. Therefore, Palker meets the limitations for the product as claimed, even though the reference does not teach the same intended use for the product.

Information Disclosure Statement

The information disclosure statement filed 11/2/2005 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered. No copies have been received from any source.

The following references are cited as illustrating the state of the art at the time of the invention:

Burstein et al US 5897991; and Sakashita et al (European Journal of Cancer 37:204-209, 2001); for teaching increased expression of GLUT1 on malignant cell surfaces.

Wood et al (British Journal of Nutrition 89:3-9, 2003); Vannucci et al (Glia 21:2-21, 1997), Brown (Journal of Inherited Metabolic Diseases 23:237-246, 2000); and Young et al (American Journal of Cardiology 83:25H-30H, 1999); as reviews indicating the variety of tissues expressing GLUT1 and some of the regulation of GLUT1 activity.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is 571-

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272-0906. The examiner can normally be reached on varying dates and times; please leave a message.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mary E Mosher, Ph.D./
Primary Examiner, Art Unit 1648

10/31/08